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Massachusetts Department of Public Health
Minutes of the Drug Formulary Commission
Meeting of Thursday, November 5, 2015
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street, Boston, MA

Date of Meeting: Thursday, November 5, 2015
Beginning Time: 2:12 PM
Ending Time: 4:52 PM

Advisory Council Members Present: The following eleven (11) appointed members of the Drug Formulary Commission attended on November 5, 2015, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Associate Commissioner Lindsey Tucker (Chair); Dr. Douglas Brandoff; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Dr. Kenneth Freedman; Dr. Paul Jeffrey; Dr. Virginia Lemay; Cindy Steinberg; Dr. Jeffrey Supko; Tammy Thomas; Dr. Alexander Walker.

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1. Welcome and Introductions

Department of Public Health (DPH) Associate Commissioner and Advisory Council Chair Lindsey Tucker called the meeting to order at 2:12PM and provided brief introductory remarks.

Ms. Tucker reminded the attendees that this is a recorded, public hearing, and confirmed that no one in audience was recording.

Ms. Tucker summarized the October 15, 2015 meeting, including discussion on comments and written testimony received from stakeholders. She reminded the attendees that written testimony and minutes are available online. She reminded the members of discussion regarding legislative intent of therapeutically equivalent substitutes; criteria and process of determining how to place drug on formulary as substitute; and summarized the development of the formulary, which consists of 3 components: which groups of drugs have heightened public health risk, which drugs to be identified as therapeutically equivalent substitutes to those with of heightened risk, and development of a crosswalk leading to the formulary.

Ms. Tucker set forth the goals of today's meeting

- Amended monograph
  - Filtering questions
  - Approval of therapeutic equivalent criteria in monograph
  - Formulary is a tool to be used, not mandatory for prescribers to utilize
- Initial presentation of data presented to council this week

2. Approval of Minutes

Ms. Tucker called for approval of the minutes from the October 15, 2015 meeting.

- Motion: Dr. Jeffrey
- Second: Dr. Brandoff
- Suggested changes
  - Page 9: "Corchrin" reviews should be *Cochrane Reviews*
- All in favor: everyone excluding Dr. Sapko and Lindsey Tucker (abstaining, not present at last meeting)

3. Evaluation Criteria

Ms. Tucker began a discussion of Evaluation Criteria, by introducing David M. Dunn for a presentation on Therapeutically Equivalent Substitution Criteria, including an updated monograph.

Mr. Dunn began his presentation by reviewing the criteria for therapeutic equivalence, and introducing the work of Virginia Lemay and residents at URI who tested the monograph application in practice.

Mr. Dunn then discussed the development of a draft formulary. He described the formulary as a guidance document for the prescribing community, establishing clear, transparent process utilizing these criteria. Mr. Dunn noted that the formulary is voluntary for physicians; that insurance must pay for these new products in equal measure to the drug for which they are substituted; and that pharmacists must dispense the substitute unless "NO substitute" is documented on prescription.

Discussion on the requirements for insurers continued. Mr. Dunn noted that the legislation called for no patient cost sharing, and pointed out that there has been some discussion with BORP and BORiM to develop training programs for pharmacists and physicians in light of a challenge that for Schedule 2 medications, pharmacists cannot substitute without a new prescription from the practitioner; we may need to work with the Board to make changes to this statute

Ms. Steinberg asked for clarification about whether prescriber or pharmacist will be making the change; will there be new regulations to work around this?

Dr. Brandoff clarified that he understood that the prescriber would be making the changes to the prescription, as these regulations exist prohibiting pharmacist from making change to Schedule 2 prescriptions.

Mr. Dunn stated that the large focus would be on educating prescribers on this new process; key access issues with insurance coverage and access to medications.

Attorney Rodman stated that the Department is not sure how this will be addressed just yet; but that we are not able to use regulations to get around; if a prescriber chooses the drug for which the pharmacists must substitute without indicating "no substitutions".

Dr. Jeffrey asked whether this will be something covered by state-funded plans (e.g. MassHealth); if an interchange is not covered by insurance, is this considered as "not less favorable"; will the language in the bill remove the necessity for prior authorization of certain doses of opiates, creating opportunity for misinterpretation?

Ms. Thomas stated that chapter 258 only requires fully insured plans, not self-funded plans to cover the substitute.

Dr. Doyle asked how this would affect Medicare Part D; will we be working with Medicare Part D plans?

Ms. Tucker stated that these were good questions, and that this issue was still something we need to work out.

Dr. Brandoff asked whether there would still be a limit on number of days supply, tablets and formulations, etc.

Ms. Tucker stated that this was yet to be determined, and redirected the conversation from fully-insured vs. self-insured for another meeting.

Mr. Dunn stated that tamper-proof products create more flexibility and improve safety in the Commonwealth in two steps:

- Step 1: Provide pharmacists with the tools to improve safety
- Step 2: Determining therapeutic equivalence; need to provide transparency.

4. Drug Monograph

Mr Dunn led the discussion of the draft monograph. He acknowledged commission member Dr. Steve Feldman's work in the current draft. Mr. Dunn informed the members that the draft monograph for review had been updated with member comments and model language added similar to the FDA guidelines for manufacturers and FDA criteria for how they determine approval for ADF products.

Mr. Dunn led a discussion of the proposed draft monograph for review. Commission members comments were captured by pharmacy intern V. Yoon on the screen in track changes for commission members and the audience to view.

Mr. Dunn informed the members of a change to the filtering questions. The members were informed of a change from 2 filtering questions to 1 "is there an ADF formulation for that drug"; removing the "volume" question. Mr. Dunn indicated that staff , didn't want to disadvantage any drug based on its volume; thought it better that if there is an ADF product it should be brought to the commission. The Comission members had concerns regarding the filtering questions and the prioritization of the work involved in reviewing the 381 opioids in schedule II and schedule III.

The Commission members conducted a section be section review of the proposed draft monograph. The Commission members debated the issue of therapeutic equivalence and the impact it will have. Commission member Supko indicated a desire to be consistent with practice standards utilizing the FDA definition of therapeutic equivalence. The commission also had concerns over the inclusion of cost as part of the monograph. Deputy Counsel R. Rodman informed that the commission is required to consider cost. The members were concerned on how cost of therapy would be compared and to the impact cost could have on access.

Ms. Tucker called for approval of the monograph as amended by the members .

- Motion: Dr. Freedman
- Second: Dr. Doyle
- All in favor: unanimous

Monograph approved at 3:50PM

Ms. Tucker indicated that there would be a 10 minute break. Members returned at 4:00PM.

Dr. Freedman discussed the monograph further.

Dr. Doyle agreed with Dr. Freedman to come back to it

Dr. Carr pointed out a typo in the draft monograph

- Table mentioned has been removed

Mr. Dunn discussed antagonist and agonist/novel (ADF/non-ADF) nomenclature, clarifying the terms

5. Inclusion of Drug Products with FDA Approved Labeling in Formulary 4:00PM

Mr. Dunn moved into a discussion on Inclusion of Drug Products with FDA Approved Labeling. Mr. Dunn noted that the FDA has a comprehensive review process for manufacturers to comply with in order to be approved by the FDA to label their products as abuse deterrent formulation (ADF).

Mr. Dunn then reviewed with the Commission four drugs that have an approved FDA labeling.

Mr. Dunn then asked if the Commission would like to place all Schedule II and III drug products with FDA approved ADF labeling on the drug formulary as therapeutically equivalent substitutes.

Dr. Freedman asked for simplification of the meaning of abuse deterrent formulation (ADF) and if these drugs went through the monograph process would the Commission find versus what the FDA found.

Mr. Dunn explained that by voting to include these drugs onto the formulary, this would be given the process of developing a cross-walk. Drugs that the Commission has already determined as possessing a heightened public health risk would appear in one column and drug that are considered abuse deterrent would be places in a second column. Once complete the Commission would then begin the process of matching these medications into a therapeutically equivalent crosswalk.

Dr. Brandoff suggested the Commission due their due diligence and put each of these drugs through the monograph review and that this would also provide information for prescribers to review and lead to increase utilization.

After much discussion, the Commission decided not to place these drugs on formulary until after a monograph was developed and reviewed by the Commission.

6. Update Data Requests 4:20pm

Ms. Tucker reminded Commission Members that at their last meeting we indicated that we would provide them with an update on the data requests that that were submitted by Commission members. In addition to their request, Ms. Tucker noted that we have reviewed other data sources that our staff believe would be helpful to their work and that today we will begin to review data elements that we have complied and look forward to continuing to provide the Commission with updates.

Ms. Tucker then invited Jon Mundy to provide an update.

Jon Mundy began by providing Commission Member's with a brief review of the Prescription Monitoring Program (PMP). Mr. Mundy noted that it was in 2011 that Massachusetts began requiring pharmacies to submit Schedule III – V controlled substances to the MA Online PMP. Mr. Mundy also noted that in 2015 automatic enrollment of mid-level providers, Physician Assistant (PA) and Nurse Practitioner (NP) began and that Prescriber Alerts, sent to prescribers monthly, have shown to be very helpful to prescribers based on alerts surveys sent to prescribers.

Dr. Brandoff inquired on how PA and NP are automatically enrolled. Mr. Mundy responded that it is part of the Massachusetts Controlled Substance Registration (MCSR) Process. When new practitioners apply for an MCSR they atomically get enrolled in the PMP and when practitioners renew their MCSR, if not already enrolled, they get enrolled.

Mr. Mundy presented a table, Geographic Locations of Prescriptions. This table presented a summary of schedule II and III opioid data by county for calendar year 2014. Mr. Mundy also presented the same data using a map of Massachusetts. Mr. Mundy noted that the data presented was based solely on where a patient receiving a prescription resides and the percentages did not

account for demographic variables such as nursing homes or rehabilitation facilities that could result in differences in opioid prescribing by county. Mr. Mundy also noted that county population was not taken into account to scale the results; however the county percentage of total Massachusetts population is inset.

Mr. Mundy did a review of Drug Formulary Commission data requests and given the amount of work already completed by the Commission to date, Mr. Mundy wanted to review these request to see if they believed the information was still relevant to completing their tasks and to clarify some of the request to make sure we would be providing the information they were seeking.

After review and discussion, the following data requested determined no longer relevant and deleted: Patient-Specific Overdose Death Data Linked to PMP, Massachusetts All Payer Claims Database, and Opioid Drugs Associated with Emergency Department Visits for Opioid Overdose.

Mr. Mundy thanked the Commission for their review and indicted to Ms. Tucker his presentation was complete.

7. Closing Remarks; Adjournment

Ms. Tucker thanked the Commission members for their participation today and reminded all members of the importance of letting us know if they would not be able to make a meeting.

Being no further business before the Commission, Ms. Tucker asked for a motion to adjourn.

- Motion: Dr. Jeffrey
- Second: Dr. Brandoff
- All in favor: unanimous consent

The Drug Formulary Commission meeting concluded at the time of 4:52PM.

Documents Presented to DFC at the *November 5, 2015* Meeting

Documents can be found at:
http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/drug-formulary-commission.html